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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,766	06/20/2002	Martinas Kuslys	112843-043	2286

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EXAMINER

HINES, JANA A

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 08/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/088,766

Applicant(s)

KUSLYS ET AL.

Examiner

Ja-Na Hines

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1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2006.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6-10 and 13-20 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1, 3, 4, 6-10, and 13-20 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. The amendments filed May 23, 2006 have been entered. Claims 3-4 and 6-9 have been amended. Claims 2, 5 and 11-12 have been cancelled. Claims 1, 3-4, 6-10 and 13-20 are under consideration in this office action.

Withdrawal of Rejections

2. The following rejections have been withdrawn in view of applicants' amendments and arguments:

a) The rejection of claims 1,3,4,6-10 and 12-20 under 35 U.S.C. 112, first paragraph, and

b) The rejection of claims 3-4, 6-9 and 12 under 35 U.S.C. 112, second paragraph.

Response to Arguments

3. Applicant's arguments filed May 23, 2006 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The rejection of claims 1, 3-4, 6-10 and 13-20 under 35 U.S.C. 103(a) as being unpatentable over JP-002158762 in view of Erdmann et al., EP 97201607.5 (May 27, 1995) [using the priority document of WO 98/53702 and US Patent 6,787,158] is maintained for reasons already of record. The rejection is on the grounds that it would have been prima facie obvious at the time of applicants' invention to modify the composition of JP-002158762 by exchanging the whey powder for hydrolyzed sweet whey protein from which caseino-glyco-macropeptide has been removed and administering the composition.

Applicants' assert that JP-002158762 does not primarily pertain to infant formula for healthy babies. However it is the examiner's position that the instant claims do not distinguish the population of infants. The claims are drawn to a composition for an infant formula. JP-002158762 teach an infant formula composition, thus the composition clearly has the capability of meeting the intend use of an infant formula. In response to applicant's argument that JP-002158762 does not primarily pertain to infant formula for healthy babies, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Furthermore, the MPEP section 2123 teaches that patents are relevant as prior art for all they contain, "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." *In re*

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Heck, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989).

Therefore applicant's argument is not persuasive especially when considering that the patent discloses compositions comprising the many of instantly claimed components.

Applicants' argue that JP-002158762 does not teach or suggest using hydrolyzed sweet whey protein or a milk protein having 5% or more of the instantly claimed amino acids. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicants' are reminded that the rejection is over JP-002158762 and Erdmann et al. JP-002158762 teach different concentrations for the amino acids such as tryptophan. No more than routine skill is involved in adjusting the amount or concentration of the claimed composition, when success would be reasonably expected. Furthermore, different concentrations of the amino acids are not viewed as limitations imparting patentability.

Applicants' assert that JP-002158762 teaches away from the invention because JP-002158762 teaches the addition of free threonine. However, it is the examiner's position that disclosed examples and preferred embodiments do not constitute a

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teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). The addition of free threonine does not teach away from the instant claims. The instant claims recite "comprising" and this transitional term is synonymous with "including," "containing," or "characterized by," and is inclusive or open-ended and does not exclude additional, unrecited elements such as different amino acids or minerals or method steps.

Furthermore, "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). The invention was directed to an epoxy impregnated fiber-reinforced printed circuit material. The applied prior art reference taught a printed circuit material similar to that of the claims but impregnated with polyester-imide resin instead of epoxy. The reference, however, disclosed that epoxy was known for this use, but that epoxy impregnated circuit boards have "relatively acceptable dimensional stability" and "some degree of flexibility," but are inferior to circuit boards impregnated with polyester-imide resins. The court upheld the rejection concluding that applicant's argument that the reference teaches away from using epoxy was insufficient to overcome the rejection since "Gurley asserted no discovery beyond what was known in the art." 27 F.3d at 554, 31 USPQ2d at 1132. Therefore contrary to applicants' argument, the prior art does not teach away from the instant claims. Therefore applicants' argument is not persuasive.

Applicants argue that Erdmann does not teach the use of hydrolyzed sweet whey. Applicants state that the process of Erdmann is the same process disclosed by

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the instant specification. However that instant specification at page 5, lines 6-10 state that the hydrolysis process may be carried out as desired and is known in the art. The specification discloses using proteases such as Alacase and/or Neutrase in the hydrolysis process to create the hydrolyzed product. Similarly, Erdmann teaches hydrolysis using a protease. Therefore, contrary to applicants' statements, the process of making hydrolyzed sweet whey both well known in the prior art and disclosed by Erdmann. Applicants refer to the removal of caseino-glyco-macropeptide. However, Erdmann specifically teaches the separation of the caseino-glyco-macropeptide from the whey protein; thereby meeting the limitations of the claim contrary to applicants statements. Applicant is reminded that the instant specification at page 4, lines 33 that the treatment to remove caseino-glyco-macropeptide from sweet whey can be accomplished by any suitable method. Similarly, Erdmann teaches that hydrolyzed sweet whey can be obtained after the extraction or separation of the caseino-glyco-macropeptide. Therefore, applicants' arguments about the hydrolyzed sweet whey protein from which caseino-glyco-macropeptide has been removed are not persuasive because the creation of hydrolyzed sweet whey protein from which caseino-glyco-macropeptide has been removed is known in the art; thus the rejection is maintained

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in

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the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, no more than routine skill would have been required to exchange the whey powder which is derived from sweet whey, since the use of a known member of a class of milk proteins or whey products in a composition is not patentable if other whey products from the milk protein class were known to be useful in infant compositions. Furthermore, no more than routine skill is required to adjust the amount of a component of the claimed composition to suit a particular starting material in order to achieve the results taught in the prior art. Moreover there would have been a reasonable expectation of success in the exchange since the art teaches that the hydrolyzed sweet whey protein has a very desirable amino acid profile and shows a reduction in threonine and an enrichment in aromatic amino acids as compared to whey.

Conclusion

5. No claims allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
July 19, 2006


NITA MINNIFIELD
PRIMARY EXAMINER
7/27/06